

Docket No.: 64343(70403)  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
Steven Kritzler

Application No.: 10/553,852

Confirmation No.: 1053

Filed: October 19, 2005

Art Unit: 3727

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For: ENDOSCOPE CLEANING PAD

Examiner: L. D. Wilson

**AMENDMENT AFTER FINAL ACTION UNDER 37 C.F.R. 1.116**

MS AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir/Madam:

**INTRODUCTORY COMMENTS**

In response to the Office Action dated February 16, 2010 (the "Action"), finally rejecting claims 45-85, please amend the above-identified U.S. patent application as follows:

**Amendments to the Claims** are reflected in the listing of claims which begins on page 2 of this paper.

**Remarks/Arguments** begin on page 8 of this paper.

### **AMENDMENTS TO THE CLAIMS**

This listing of claims will replace all prior versions of claims in the application.

1-44. (previously cancelled)

45. (currently amended) A cleaning device for cleaning a medical instrument including: a fabric, wipe, or sponge impregnated with a composition comprising at least one enzyme, wherein the enzyme is present as a solution or a suspension in an amount of 5 to 25 %w/w of the composition, a surfactant and a humectant, wherein contaminants on said instrument are removed or distributed by said cleaning device so as to enhance the speed and efficiency of enzyme digestion.

46. (previously presented) A cleaning device according to claim 45 further including a disinfectant compatible with said at least one enzyme.

47. (previously presented) A cleaning device according to claim 45 wherein the at least one enzyme is selected from protease, alcalase, cellulase, lipolase, and combinations thereof.

48. (Canceled)

49. (currently amended) A cleaning device according to claim ~~47~~ wherein the enzyme is present as a solution or a suspension in an amount of 10 to 20 %w/w of the composition.

50. (previously presented) A cleaning device according to claim 45 wherein the humectant is selected from calcium chloride, sodium chloride, glycerine, borax, ethylene glycol, propylene glycol and combinations thereof.

51. (previously presented) A cleaning device according to claim 50 comprising glycerine as a humectant.

52. (previously presented) A cleaning device according to claim 45 wherein the humectant is present in an amount to ensure that sufficient water is absorbed to reduce any hazard which would arise from use of the enzyme in dry form.

53. (previously presented) A cleaning device according to claim 45 wherein the humectant is present in an amount to maintain activity of the enzyme during storage.

54. (previously presented) A cleaning device according to claim 53 wherein the humectant is present in the composition in an amount of 1 to 10 %w/w of the composition.

55. (previously presented) A cleaning device according to claim 54 wherein the humectant is present in the composition in an amount of 4 to 7 %w/w of the composition.

56. (previously presented) A cleaning device according to claim 45 wherein the surfactant includes at least one non-ionic surfactant.

57. (previously presented) A cleaning device according to claim 56 wherein the non-ionic surfactant is present in the composition in an amount of 5 to 45 %w/w.

58. (previously presented) A cleaning device according claim 45 wherein the surfactant is a synthetic or natural alcohol ethoxylate.

59. (previously presented) A cleaning device according to claim 45 wherein the surfactant includes at least one anionic surfactant.

60. (previously presented) A cleaning device according to claim 59 wherein the anionic surfactant is present in the composition in an amount of 5 to 15 %w/w.

61. (previously presented) A cleaning device according to claim 59 wherein the anionic surfactant is a hydrocarbon sulphonate or sulphate.

62. (previously presented) A cleaning device according to claim 45 wherein the total surfactant in the composition is in an amount of 15 to 45% w/w.

63. (previously presented) A cleaning device according to claim 45 further including a preservative.

64. (previously presented) A cleaning device according to claim 45 adapted to

i) remove at least a portion of externally adherent soiling on a surgical instrument by mechanical wiping; and

ii) to redistribute any remaining external soiling such that it is distributed as a film of thinner and more uniform thickness than on the unwiped instrument.

65. (previously presented) A cleaning device according to claim 45 adapted for use in cleaning an exterior tubular surface of a surgical instrument.

66. (previously presented) A cleaning device according to claim 45 adapted for use in cleaning an exterior tubular surface of an endoscope.

67. (previously presented) A cleaning device according to claim 45 adapted to contact a substantial arc of an external circumference of a tubular portion of the instrument.

68. (previously presented) A cleaning device according to claim 67 adapted to engage an arc of about 360 degrees of an external circumference of a tubular portion of the instrument and which is resiliently deformable in a radial direction.

69. (previously presented) A cleaning device according to claim 45 adapted to slide axially along the length of a tubular portion of the instrument so as to wipe the surface thereof.

70. (previously presented) A cleaning device according to claim 45 fabricated from hydrophilic fibres.

71. (previously presented) A cleaning device according to claim 45 fabricated from polymeric material.

72. (previously presented) A cleaning device according to claim 45 composed of viscose fibres and polypropylene fibres.

73. (previously presented) A cleaning device according to claim 72 wherein the viscose fibres and polypropylene fibres form a homogeneous mixture tangled by a needling technique to form a low density web with substantially no free fly away fibres.

74. (previously presented) A cleaning device according to claim 45 in the form of a wipe, or roll of wipes, fabricated from a polymeric foam, textile, paper or hybrid material.

75. (previously presented) A cleaning device for cleaning a medical instrument consisting in a fabric, wipe or sponge impregnated with a hygroscopic enzyme cleaning formulation containing one or more enzymes, one or more surfactants and an enzyme stabilising system.

76. (previously presented) A cleaning device according to claim 45 for use in cleaning an exterior surface of a tubular portion of an endoscope in need of said cleaning, said device including a pad having a groove extending from one end of the pad to an opposite end and adapted resiliently to engage the exterior surface of the tubular portion of the endoscope exterior surface, the pad being adapted alone or with a complementary pad to substantially encircle the exterior surface of the tubular portion and being resiliently deformable so as to engage the exterior surface of the encircled portion, whereby to uniformly wipe said exterior surface as the device is slid longitudinally along the endoscope tube.

77. (previously presented) A cleaning device according to claim 76 wherein the pad is formed of a needle felt and has two spaced apart parallel grooves each of arcuate cross-section which may be folded into alignment on opposite sides of a tubular axis to form a tubular tunnel resiliently engaging the exterior surface of a tubular portion of an endoscope about its circumference.

78. (previously presented) A cleaning device according to claim 77 which may be folded about a longitudinal fold seam.

79. (previously presented) A cleaning device according to claim 45 fabricated from a non-woven fabric and impregnated with one or more enzymes, one or more surfactants and at least one humectant.

80. (previously presented) A cleaning device according to claim 79 fabricated from a non-woven fabric and impregnated with a plurality of enzymes, a plurality of surfactants and at least one humectant.

81. (previously presented) A package containing a cleaning device for cleaning a surgical instrument, said cleaning device including at least one single use fabric, wipe or sponge impregnated with an enzyme, a surfactant, and a humectant.

82. (currently amended) A package according to claim 81 wherein the package is moisture permeable.

83. (previously presented) A method of cleaning the exterior surface of a surgical instrument in need thereof, said method including the steps of

- i) wiping the exterior surface, wherein a resilient pad or a wipe is pressed against an exterior surface of the surgical instrument and slid longitudinally to mechanically remove gross soiling and at the same

time redistribute any residue remaining to a substantially uniform thickness, while at the same time

ii) subjecting the surface to treatment with an enzyme and a surfactant, wherein the enzyme is present as a solution or a suspension in an amount of 5 to 25 %w/w of the composition.

84. (previously presented) A method according to claim 83 wherein a resilient pad or wipe is held around a tubular portion of the surgical instrument in a manner which exerts a force acting radially towards an axis of the tubular portion of the surgical instrument.

85. (previously presented) A method according to claim 84 wherein the residue is redistributed to a more uniform thickness about a circumference and a length of the tubular portion of the surgical instrument.

### **REMARKS**

Claims 45-85 are pending. Claims 45, 82 and 83 are amended herewith. Claim 82 is amended merely to correct punctuation. Claim 48 is canceled without prejudice. Amendment of any claim herein is not to be construed as acquiescence to any of the rejections/objections set forth in the Office Action, and was done to expedite prosecution of the application. Applicants make these amendments without prejudice to pursuing the original subject matter of this application in a later filed application claiming benefit of the instant application, including without prejudice to any determination of equivalents of the claimed subject matter. Support for these amendments appears throughout the specification and claims as filed. No new matter is introduced by these amendments.

#### **Rejections under 35 U.S.C. § 102(e)**

Claims 45-85 are rejected as allegedly being anticipated by Padlo et al. (US 7,235,250) and/or Pablo [sic] et al. (US 2004/007660). It is asserted in the Action that Padlo discloses a cleaning device having a fabric, wipe, or sponge which includes at least one enzyme, a surfactant and a humectant. Applicants traverse.

None of the Examples exemplified in Padlo disclose a composition containing an enzyme. More significantly, none of the Examples exemplify a composition comprising at least one enzyme, a surfactant and a humectant, as claimed. Applicants submit that there is simply no explicit teaching in Padlo of the specific combination of elements recited in Applicants' claimed subject matter in Padlo's cosmetic compositions. Nonetheless, Applicants have amended independent claims 45 and 83 to incorporate the claim element (supported throughout the application and claims as originally filed, including original claim 45) that the "enzyme is present as a solution or a suspension in an amount of 5 to 25 %w/w of the composition" and in claim 45 the claim element (supported throughout the application and claims as originally filed, including at page 5, lines 5-8) that "wherein contaminants on said instrument are removed or distributed by said cleaning device so as to enhance the speed and efficiency of enzyme digestion."



The amendment to claim 45 includes the specific range of enzyme by weight that is included in the cleaning composition of the present invention. Claim 83 has also been amended for consistency to include the specific range of enzyme by weight. The further amendment to claim 45 highlights the essential function of the enzyme in the composition of the present invention and has been amended to focus more clearly on a key object of the invention.

Applicants submit that the presently claimed invention is novel in view of Padlo as in the Padlo teaching an enzyme is not present in a solution or suspension in an amount of 5 to 25% w/w. Indeed, as noted in paragraph [0068] of Padlo as referred to by the Examiner, an enzyme is only optionally present in the personal care composition of this prior art as a mere benefit agent with no particular quantity indicated and serves no essential purpose in the invention. As indicated previously, none of the Examples of Padlo contain an enzyme, nor is one remotely required for a digestive cleansing function as used in the present invention. The personal care compositions described and exemplified in Padlo are cold creams, skin moisturisers, liquid foundation and such, which have no requirement for a cleansing action, and in fact would be unsuitable for endoscopic cleaning applications, and Padlo is devoid of any teaching of enzyme levels as recited by Applicants' claimed subject matter. Furthermore, the enzyme in the cleaning composition of the present invention is present in a specific quantity to necessarily perform an essential digestive cleansing function. The cleaning device of the present invention is designed such that the contaminants on an article cleaned by the device are distributed in such a way by so as to promote this enzyme digestion. This is simply not taught by Padlo.

In summary, each and every claim element of Applicants' claimed subject matter (as amended herewith) is not taught by Padlo. Based on at least the forgoing reasons, Applicants respectfully submit that the rejection be withdrawn.

In view of the above amendment, Applicants believe the pending application is in condition for allowance. Should any of the claims not be found to be allowable, the Examiner is requested to telephone Applicants' undersigned representative at the number below. Applicants thank the Examiner in advance for this courtesy. The Director is hereby authorized to charge or credit any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. 64343NAT(70403).

Dated: May 14, 2010

Respectfully submitted,

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